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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.
530 VIRGINIA ROAD
P.O. BOX 9133
CONCORD, MA 01742-9133

EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/043,436	LE ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-12 and 14-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-12 and 14-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 4/11/05, has been entered.
Claims 2, 6 and 13 have been canceled.
Claims 1, 3-5, 7-8, 11-12, and 14-15 have been amended
Claims 16-25 have been added.

Claims 1, 3-5, 7-12 and 14-25 are pending.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Action will be in response to applicant's arguments, filed 4/11/05.
The rejections of record can be found in the previous Office Action, mailed 10/7/04.

3. Applicant's assertions concerning priority of the instant application have been fully considered but are not found convincing essentially for the reasons of record.

Applicant relies upon TNF-α-mediated human diseases and the disclosure of "alcohol-induced hepatitis", to support the recitation of "hepatitis-pathologies", as previously claimed, or "TNF-α-mediated hepatitis" or "hepatitis", as currently claimed.

It is acknowledged that the mechanism of treatment via TNF-α-specific antibodies would be the same regardless of the TNF-α –mediated disease in the context of neutralizing TNF-α-mediated inflammation.

However, the issue of priority and new matter below is concerned with the written description of the diseases or conditions targeted in the claimed methods.

The instant claims now recite limitations which were not clearly disclosed in the priority applications as well as the specification as-filed, and would have changed the scope of the priority applications and do change the scope of the instant disclosure as-filed.

Neither the priority applications nor the instant application have provides a sufficient description of a representative number of species to represent the entire genus of "hepatitis" or "TNF-α-mediated hepatitis", as currently claimed.

It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

Therefore, reliance upon the genus of "TNF-α-mediated human diseases" and the disclosure of the species "alcohol-induced hepatitis", does not support the recitation of "hepatitis" or "TNF-α-mediated hepatitis", as currently claimed or "hepatitis-pathologies", as previously claimed.

As pointed out previously for example, it appears that the disclosure of "hepatitis pathologies" was limited to the instant claims only and page 59, Section (F) of the instant specification discloses "(F) alcohol-induced hepatitis".

Again, it is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977).

The filing date of the instant claims is deemed to be the filing date of the instant application USSN 10/043,436, filed 1/10/02 with respect to "hepatitis-pathologies".

In addition, while applicant asserts that entitlement of priority should be granted for applicant's own priority application / patent USSN 08/192,861, now U.S. Patent No. 5,919,452 (i.e. 2/4/94), which was employed in the prior art rejection of record,
Applicant is reminded that priority and written description differ from prior art determinations.

Also, applicant is reminded that a species reads on a genus.

Therefore, prior art referenced methods of treating "alcohol-induced hepatitis" anticipates the more generic recitation of "hepatitis" or "TNF-α-mediated hepatitis", as currently claimed or "hepatitis-pathologies", as previously claimed.

Applicant's arguments concerning priority of the instant claims, drawn to "hepatitis" or "TNF-α-mediated hepatitis" have not been found persuasive.

Again, if applicant desires priority prior to the instant application, applicant is invited to point out and provide documentary support for the priority of the instant claims.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C.§ 112, first paragraph.

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The amendment filed 4/11/05, is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "hepatitis" or "TNF-α-mediated hepatitis".

For the reasons set forth above in Section 3, it does not appear the priority applications nor the instant application provide sufficient written description for treating "hepatitis" or "TNF-α-mediated hepatitis", as currently claimed.

As pointed out previously for example, it appears that the disclosure of "hepatitis pathologies" was limited to the instant claims only and page 59, Section (F) of the instant specification discloses "(F) alcohol-induced hepatitis".

Amending the specification to disclose "hepatitis" or "TNF-α-mediated hepatitis" rather than "hepatitis pathologies" is a departure from the instant disclosure as filed and changes the scope of the instant disclosure, particularly in the absence of sufficient evidence to the contrary.

As applicant acknowledges, hepatitis is defined as an inflammation of the liver from any cause (see The Merck Manual of Medical Information, Berkow et al., Pocket Books, pages 571-574, 1997; Exhibit A) and that the specification does not provide a specific example direct to TNF α-mediated hepatitis.

Applicant instant disclosure as filed did not provide a sufficient written description or definition of "hepatitis pathologies" nor "TNF-mediated hepatitis" as well as the broader genus of "hepatitis" as filed.

Therefore, reliance upon the genus of "TNF-α-mediated human diseases", "hepatitis-pathologies" as previously claimed (but not described in the specification) and the disclosure of the species "alcohol-induced hepatitis", does not support the recitation of "hepatitis" or "TNF-α-mediated hepatitis", as currently amended in the instant specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Alternatively, applicant is invited to identify the written support for the claimed recitation of "hepatitis" in the specification as-filed.

6. Claims 1, 3-5, 7-12 and 14-25 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.
The specification as originally filed does not provide support for the invention as now claimed: "hepatitis" or "TNF-α-mediated hepatitis".

Applicant's amendment, filed 4/11/05, asserts that no new matter has been added and relies upon the disclosure of page 16, lines 15-19 and page 57, line 17 to page 59, line 14 of the instant specification for support of the "hepatitis" or "TNF-α-mediated hepatitis".

Applicant relies upon TNF-α-mediated human diseases and the disclosure of "alcohol-induced hepatitis", to support the recitation of "hepatitis-pathologies", as previously claimed, or "hepatitis", as currently claimed.

It is acknowledged that the mechanism of treatment via TNF-α-specific antibodies would be the same regardless of the TNF-α –mediated disease in the context of neutralizing TNF-α-mediated inflammation.

However, the issue of priority above and new matter herein is concerned with the written description of the diseases or conditions targeted in the claimed methods.

The instant claims now recite limitations which were not clearly disclosed in the priority applications as well as the specification as-filed, and now change the scope of the priority applications and the instant disclosure as-filed.

Neither the priority applications nor the instant application have provides a sufficient description of a representative number of species to represent the entire genus of "hepatitis" or "TNF-α-mediated hepatitis", as currently claimed.

It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972) and MPEP 2163.05.

Therefore, reliance upon the genus of TNF-α-mediated human diseases and the disclosure of the species "alcohol-induced hepatitis", as well as the previous recitation of "hepatitis pathologies" does not support the recitation of "hepatitis" or "TNF-α-mediated hepatitis", as currently claimed.

Again, it is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977).

The specification as filed does not provide a sufficient written description or set forth the metes and bounds of this phrase. The specification does not provide blazemarks nor direction for the instant methods encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above.
See MPEP 714.02 and 2163.06

7. Claims 1, 3-5, 7-12 and 14-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention
It is apparent that the cA2 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

Applicant's arguments and comments, filed 4/1/05, concerning the enablement of the cA2 antibody is acknowledged.

Declarant Vilcek's indication that there was a policy of New York University to furnish third parties with a sample of the starting material A2 antibody (see Vilcek Declaration filed under 37 CFR 1.132, filed 4/1/05) is acknowledged.

However, biological materials must be known and readily available to the public (See MPEP 2404.01). Neither concept alone is sufficient. The fact that applicant and other members of the public were able to obtain the materials in question from a given source (e.g. New York University or a recognized depository) prior to and after the filing date of the application does not establish the upon issuance of a patent on the application that such material would continue to be accessible to the public. The applicant did not make of record any of the facts and circumstances surrounding the access to the biological materials from the depository, nor is there any evidence as to the depository's policy regarding the material if a patent would be granted. Further, there are no assurances that New York University would allow unlimited access to the material if the application has matured into a patent. Also, it is noted that the claims are drawn to the particular chimeric cA2 antibody and not the mouse A2 antibody.

In the absence of evidence that the cA2 antibody is readily available to the public and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, applicant's arguments are not persuasive and the rejection would be maintained.

It is noted that it is unclear if a cell line which has the exact structural and chemical identity of the cA2 antibody can be reproducibly isolated without undue experimentation. Replication of the claimed chimeric cA2 antibody is an unpredictable event. Further, a particular biological material or cell line can undergo changes resulting in microheterogeneity. Therefore, a suitable deposit or alternative means for patent purposes is required. Without a publicly available deposit of the appropriate cell line for the claimed cA2 antibody, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed.

As indicated previously, given the disclosure and the claims encompassing the instant cA2 antibody set forth in U.S. Patent No. 5,919,452; the conditions for the enablement of biological materials under 35 USC 112, first paragraph, with respect to cA2 appear to have been satisfied.

However in the interest of clarity and compact prosecution, again applicant is required to make the record clear exactly what is the scope of the instantly claimed cA2.

It is noted that the requirements under 35 USC 112, first paragraph, for the claimed cA2 antibody was not satisfied by the deposit of the cA2 antibody in the priority applications, some of which are patented now.

However, the instant record should indicate the parameters that have satisfied the enablement requirements under 35 USC 112, first paragraph, for the cA2 antibody.

8. Applicant's amended claims in conjunction with applicant's arguments, filed 4/11/05 have obviated the previous rejections under 35 U.S.C. 112, first paragraph, enablement, with respect to the "TNF-α specificity" and "TNF-α-mediated hepatitis" (versus "hepatitis pathologies").

9. Applicant's amended claim 15, filed 4/11/05, has obviated the previous objection under 37 CFR 1.75 as being a substantial duplicate of claim 11.

10. Claims 1, 3-5, 7-12 and 14-25 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1, 3-5, 7-12 and 14-25 are indefinite in the recitation of "cA2" because its characteristics are not known. The use of "cA2" monoclonal antibody as the sole means of identifying the claimed antibody renders the claim indefinite because "cA2" is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designation s to define completely distinct hybridomas / cell lines.

Applicant is invited to clarify the metes and bounds of the claimed cA2 antibody.

Applicant's arguments and comments, filed 4/11/05, have been fully considered concerning the indefiniteness of the instant "cA2".

However in the interest of clarity and compact prosecution, again applicant is required to make the record clear exactly what is the metes and bounds of the instantly claimed cA2.

As indicated previously and above,

given the disclosure and the claims encompassing the instant cA2 antibody set forth in U.S. Patent No. 5,919,452; the conditions for the enablement of biological materials under 35 USC 112, first paragraph, with respect to cA2 appear to have been satisfied.

Applicant is invited to clarify the instant record.

It is noted that the requirements under 35 USC 112, first and second paragraphs, for the claimed cA2 antibody have been satisfied in the priority applications, some of which are patented now.

However, the instant record should indicate the parameters that have satisfied the requirement under 35 USC § 112, second paragraph as well as the enablement requirements under 35 USC 112, first paragraph, for the cA2 antibody.

B) The previous rejection under 35 USC 112, second paragraph, with respect to the recitation of "hepatitis pathologies" has been obviated by applicant's amended claims, filed 4/11/05.

C) Claims 1, 3-5, 7-12 and 14-25 are indefinite in the recitation of "TNFα-mediated hepatitis" because the metes and bounds of said "TNFα-mediated hepatitis" is ill-defined and ambiguous.

As pointed out previously, it appears that the disclosure as filed only provided for "(F) alcohol-induced hepatitis" and not the more generic recitation of "TNFα-mediated hepatitis", as currently recited.

In addition, it is noted that applicant's amendment acknowledges that the specification does not provide a specifi example directed to "TNFα-mediated hepatitis" (see page 20, paragraph 2 of applicant's amendment, filed 4/11/05).

There is insufficient description of the nature and targeted "TNFα-mediated hepatitis" to apprise the ordinary artisan of the metes and bounds of the claimed methods.

D) Claims 16 and 18-19 are indefinite in the recitation of "neutralizing epitope of human TNFα" thereof because the claims fails to state sufficient structure and/or function which is to be achieved that defines the metes and bounds of the "neutralizing epitope of human TNFα", which renders the claims indefinite. The phrase does not define the claimed "neutralizing activity" nor the structure of the claimed "neutralizing epitope" and the specification does not provide a standard for ascertaining the requisite definition of "neutralizing epitopes", and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Applicant is invited to amend the claims to clarify that the nature and metes and bounds of the claimed "neutralizing epitope of human TNFα".

E) Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

11. Claims 1, 3-5, 7-12 and 14-25 are rejected under 35 U.S.C. § 102(b) as being anticipated by Le et al. (U.S. Patent No. 5,919,452) (see entire document) essentially for the reasons of record.

Applicant's arguments, filed 4/11/05, have been fully considered but are not found convincing essentially for the reasons of record.

Applicant argues that if this reference is sufficient to qualify as prior art, it is sufficient to support to the claims for priority.

However, for the reasons of record and addressed above, the issues of priority are associated with written description, which, in turn, differ from the issues governing prior art.

The following of record is reiterated for applicant's convenience.

Le et al. teach methods of treating TNF-α-mediated diseases, including alcohol-induced hepatitis (see column 35, line 12) with TNF-α-specific antibodies, including recombinant and chimeric antibodies and the cA2 antibody specificity of the instant invention (see entire document, including Summary of the Invention, Detailed Description of the Invention and Claims). Also see Therapeutic Administration for the well known dosing and modalities of administering therapeutic antibodies of interest to meet the needs of the patients (see columns 35- 41).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat alcohol-induced hepatitis with recombinant cA2-specific antibodies.

A species anticipates a claim to a genus. See MPEP 2131.02.

Applicant's arguments have not been found persuasive.

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
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